



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

005514 HM11/1013  
FITZPATRICK CELLA HARPER & SCINTO  
30 ROCKEFELLER PLAZA  
NEW YORK NY 10112-3801

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/466,308	06/06/95	009	MERTZ M, R	1646 10/13/98
First Named Applicant	CLARK,	35 USC 154(b) term ext.	=	0 Days.

**TITLE OF INVENTION** RECOMBINANT HUMAN GRANULOCYTE MACROPHAGE - COLONY STIMULATING FACTOR (GM-CSF) (AS AMENDED)

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEES DUE	DATE DUE
1 118-6415/PCT	424-085.100	K41	UTILITY	NO	\$1320.00	01/13/99

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT.**  
**PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

I. Review the SMALL ENTITY status shown above.  
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or  
B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay FEE DUE shown above, or  
B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.  
Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/466,308 06/06/95 CLARK

S 118-6415/PCT

EXAMINER

005514 HM11/1013  
FITZPATRICK CELLA HARPER & SCINTO  
30 ROCKEFELLER PLAZA  
NEW YORK NY 10112-3801

AMENDMENT PAPER NUMBER

19

DATE MAILED:

10/13/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### NOTICE OF ALLOWABILITY

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

This communication is responsive to the response filed 7/26/98.

The allowed claim(s) is/are 1-3, 5-8, 14, 16, now renumbered 1-3, 4-7, 8, 9, respectively.

The drawings filed on \_\_\_\_\_ are acceptable.

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been  
 received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

Applicant MUST submit NEW FORMAL DRAWINGS

because the originally filed drawings were declared by applicant to be informal.

including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 7.

including changes required by the proposed drawing correction filed on \_\_\_\_\_, which has been approved by the examiner.

including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings.  
The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 8

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

Interview Summary, PTO-413

Examiner's Amendment/Comment

Examiner's Comment Regarding Requirement for Deposit of Biological Material

Examiner's Statement of Reasons for Allowance

Art Unit: 1646

1. An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Lawrence S. Perry on 10/1/98.

2. The application has been amended as follows:

**IN THE CLAIMS:**

In claim 5, line 2, after "any" insert --one--. /

In claim 6, line 2, after "any" insert --one--. /

In claim 6, line 3, after "met-ala" delete ",". /

In claim 7, line 2, after "any" insert --one--. /

In claim 8, line 2, after "any" insert --one--. /

In claim 14, line 2, after "any" insert --one--. /

In claim 16, line 2, after "any" insert --one--. /

In claim 8, line 3, delete "proceeded", substitute therefor --preceded--. /

In claim 16, line 11, delete "the", substitute therefor --a--. /

In claim 16, line 6, delete "CSF", substitute therefor --GM-CSF--. /

In claim 16, line 9, delete "CSF", substitute therefor --GM-CSF--. /

In claim 16, line 10, delete "CSF", substitute therefor --GM-CSF--. /

Art Unit: 1646

In claim 16, line 12, delete "CSF", substitute therefor --GM-CSF--. ✓

In claim 16, line 15, delete "CSF", substitute therefor --GM-CSF--. ✓

**IN THE SPECIFICATION:**

In the specification, below the title "lymphokine production and purification", please delete the amendment in Paper No. 2 (6/6/95), and substitute therefor,

-- "Cross Reference to Related Applications

This is a continuation of application Serial No. 08/287,019, filed August 8, 1994, which is a continuation of application Serial No. 08/043,322, filed April 6, 1993, now abandoned, which is a continuation of application Serial No. 07/821,668, filed January 16, 1992, now abandoned, which is a continuation of application Serial No. 07/479,014, filed January 29, 1990, now abandoned, which is a continuation of application Serial No. 06/853,807, filed March 5 1986, which is a 371 of PCT/EP85/00326, filed July 4, 1985, which is a continuation-in-part of application Serial No. 06/652,742, filed September 19, 1984, now abandoned, and a continuation-in-part of application Serial No. 06/652,447, filed September 19, 1984, now abandoned, which is a continuation of application Serial No. 06/628,342, filed July 6, 1984, now abandoned.--

On page 8, before "Fig. 6", insert -- Fig. 5 illustrates SDS-PAGE analysis of the purified CSF-

protein--.

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3. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Prema Mertz*  
Prema Mertz Ph.D.  
Patent Examiner  
Art Unit 1646  
October 2, 1998